

**REMARKS**

Claims 1-21 are all of the pending claims, with claims 1, 18, and 20 being written in independent form.

**I. Claim Rejections on Prior Art Grounds:**

The Examiner rejects:

1. claims 1, 11, 15 and 18-20 under 35 USC §103(a) as being obvious over US 5,044,372 to Anhäuser et al. ("Anhäuser") in view of DE 38 11 564 A1 to Liedtke ("Liedtke");
2. claims 2-4, 17 and 21 under 35 USC §103(a) as being obvious over Anhäuser and Liedtke, and further in view of US 4,887,611 to Rüdiger et al. ("Rüdiger");
3. claim 5 under 35 USC §103(a) as being obvious over Anhäuser and Liedtke, and further in view of US 4,450,844 to Quisno ("Quisno");
4. claim 6 under 35 USC §103(a) as being obvious over Anhäuser and Liedtke, and further in view of US RE37,934 to Hoffmann ("Hoffmann");
5. claim 7 under 35 USC §103(a) as being obvious over Anhäuser and Liedtke, and further in view of US 4,543,964 to Breneman ("Breneman");
6. claim 8 under 35 USC §103(a) as being obvious over Anhäuser and Liedtke, and further in view of NL 8701577 to van der Bend ("van der Bend");
7. claims 9, 12 and 13 under 35 USC §103(a) as being obvious over Anhäuser and Liedtke, and further in view of US 4,472,507 to Pluim, Jr. ("Pluim");
8. claims 10 and 14 under 35 USC §103(a) as being obvious over Anhäuser, Liedtke and Pluim, Jr., and further in view of US 4,158,359 to Kurokawa et al. ("Kurokawa"); and
9. claim 16 under 35 USC §103(a) as being obvious over Anhäuser and Liedtke, and further in view of US 4,809,707 to Kraft et al. ("Kraft").

Applicant respectfully traverses all of these rejections in view of the following remarks.

**A. Independent Claims 1, 18 and 20:**

Each of independent claims 1, 18 and 20 recites (albeit in different formats) that each test chamber includes:

- (1) a frame-shaped foam plastic layer "*defining at least some sidewalls of the test chamber that directly confront each other*"; and
- (2) a "*layer of adhesive*" (or "*adhesive means*") provided on the frame-shaped foam plastic layer.

An example, non-limiting embodiment of these features is depicted in Fig. 2. As shown, the frame-shaped foam plastic layer 25 defines at least some sidewalls of the test chamber 31 that directly confront each other. For example, the left sidewall faces the right sidewall without any other elements intervening between these two sidewalls. Further, a layer of adhesive 26 is provided on the outer side (or upper side in Fig. 2) of the frame-shaped foam plastic layer 25.<sup>1</sup> At least these features (as recited in each of independent claims 1, 18 and 20), in combination with the other features recited in independent claims 1, 18 and 20, are not taught or suggested by the prior art relied upon by the Examiner.

The Examiner recognizes that Anhäuser is not pertinent to the claimed “*layer of adhesive*” (or “*adhesive means*”), and therefore looks to Liedtke to allegedly teach this feature. In so doing, the Examiner concludes that it would have been obvious to a skilled artisan to place Liedtke’s adhesive layer 5 (see Fig. 1) on the outwardly directed side of Anhäuser’s locking ring 15 “*to achieve the predictable result of providing additional adhesive to further adhere the plaster to skin.*”<sup>2</sup> This rejection position is not convincing for several reasons.

#### New Examination Guidelines

Based on the details of the rejection, it is apparent that the Examiner looks to the new examination guidelines for determining obviousness under 35 USC §103 in view of the Supreme Court decision in KSR International Co. v. Teleflex Inc.<sup>3</sup> This is because the new guidelines include a list of rationales that may be used to support a finding of obviousness. And one of the listed rationales involves combining prior art elements according to known methods to yield predictable results.<sup>4</sup> This rationale requires (among other things) satisfaction of a four part test. In the situation at hand, however, at least the first part of the four part test is *not satisfied*.

In particular, the first part of the test requires that the prior art included each element claimed, with the *only difference* between the claimed invention and the prior art being the lack of actual combination of the elements in a single prior art reference. Here, the Examiner attempts to compare Liedtke’s adhesive layer 5 to the claimed adhesive layer. As shown in

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<sup>1</sup> Spec., p. 9, lines 1-9.

<sup>2</sup> Office Action, paragraph 7.

<sup>3</sup> The new examination guidelines are set forth in the Federal Register, vol. 72, no. 195, p. 57526-57535, October 10, 2007.

<sup>4</sup> *Id.* at 57529.

Fig. 1 of Liedtke, the adhesive layer 5 is provided on a foam plastic layer 4.<sup>5</sup> The foam plastic layer 4 does *not*, however, constitute a constituent part (or otherwise include) any chamber, as alleged by the Examiner. Instead, as clearly shown in Fig. 2 of the reference, the foam plastic layer 4 surrounds a support layer 1. The support layer 1 (not the foam plastic layer 4) is provided with chambers (or apertures) 2 that receive medicine.<sup>6</sup> But the support layer 1 does not have any adhesive on the skin facing surface. In this regard, Liedtke is no more relevant to the claimed invention than Anhäuser.

Furthermore, and for argument sake only, Applicant recognizes that Liedtke's foam plastic layer 4 includes a central aperture for receiving the support layer 1. Even if the central aperture were comparable to a chamber, as alleged by the Examiner, then the rejection position would still be incorrect. This is because the foam plastic layer 4 does *not* define "*at least some sidewalls of the test chamber that directly confront each other*," as claimed. Indeed, the support layer 1 (positioned in foam plastic layer 4) necessarily prevents any sidewalls of the central aperture from directly confronting each other.

In short, the asserted references disclose numerous and varied adhesive layers, but none is provided on an outwardly directed side of a frame-shaped foam plastic layer "*defining at least some sidewalls of the test chamber that directly confront each other*," as claimed. This difference in location is significant because it is in addition to the lack of actual combination of the claim elements in a single reference (which is the *only difference* permitted by the test).

Applicant notes that claim 18 recites the adhesive layer in a *means-plus-function* format. Specifically, claim 18 requires "*adhesive means for attaching the frame-shaped foam plastic layer to a test area*." In contrast, Liedtke teaches a *therapeutic device* for bringing medications into the body system of the patients. Accordingly, Liedtke's adhesive layer 5 is for attaching the device to a therapeutic area, not a "*test area*" as claimed. This difference in function is significant because it is in addition to the lack of actual combination of the claim elements in a single reference (which is the *only difference* permitted by the test).

References Teach a "Primary Adhesive" Feature Only

Applicant respectfully submits that Anhäuser and Liedtke are similar in that each teaches a "primary adhesive" feature only, wherein an adhesive is provided to secure the

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<sup>5</sup> Machine translation of Liedtke provided by Examiner, [0014].

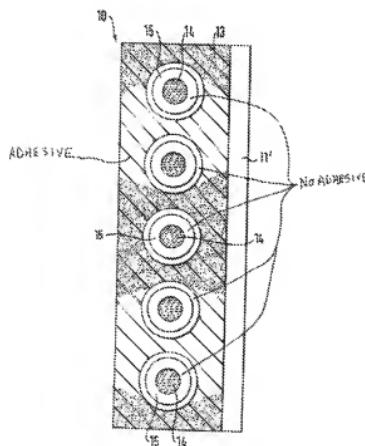
<sup>6</sup> Machine translation of Liedtke provided by Examiner, [0007] and [0014].

device to skin. But in both references, and consistent with conventional wisdom, the adhesives are provided around (but not on) the skin facing surfaces of the elements defining the chambers.

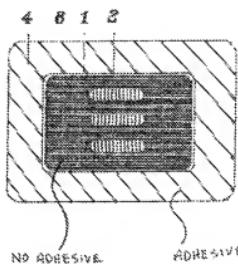
In contrast, and parting from conventional wisdom, a “secondary adhesive” feature is one in which an adhesive is provided on the skin facing surface of a chamber defining element. As compared to the conventional “primary adhesive” feature, the “secondary adhesive” feature may reduce (if not altogether prevent) a leakage of material from the individual test chambers.<sup>7</sup>

To further illustrate, Applicant prepared the following marked-up copies of Fig. 2 of Anhäuser and Fig. 2 of Liedtke for the Examiner’s review. The mark-ups include adding cross hatching to the areas where adhesive is applied to the device.

**Fig. 2 of Anhäuser**



**Fig. 2 of Liedtke**



As clearly shown, neither reference teaches a “secondary adhesive” feature. In Anhäuser, for example, adhesive is **not** applied to the locking rings 15, which is the element

<sup>7</sup> Spec., p. 5, lines 15+.

defining the chambers. And in Liedtke, adhesive is *not* applied to the support layer 1, which is the element defining the chambers (or apertures) 2.

References Teach Away From Any Combination

In this case, the references take mutually exclusive paths and reach different solutions to practically and conceptually different problems. On the one hand, the primary reference to Anhäuser teaches a *diagnostic test device* including a receiving device 14 that is loaded with a test substance.<sup>8</sup> The intended purpose of the device is to apply the test substance to a patient's skin. On the other hand, the secondary reference to Liedtke teaches a *therapeutic device* for bringing medications into the body system of the patients through a transdermal route. The two concepts (i.e., supplying a test substance to the skin *versus* bringing medications into the body) are fundamentally different, and therefore it would not be logical to combine the references in the manner suggested by the Examiner.

**B. Dependent Claims 2 and 21:**

Each of dependent claims 2 and 21 recites that the cover layer is a plastic layer with “*blister bubbles*.” An example, non-limiting embodiment of this feature is depicted in Fig. 3. Here, the blister bubble is designated with reference character 33. At least this feature (as recited in each of claims 2 and 21), is not taught or suggested by the prior art relied upon by the Examiner.

The Examiner recognizes that Anhäuser and Liedtke are not pertinent to the claimed blister bubbles, and therefore looks to Rüdiger to allegedly teach this feature. This rejection position is not convincing.

Rüdiger does *not* teach or suggest blister bubbles. The term “*blister bubbles*” refers to a blister pack with cavities which are created from rolls of flat plastic sheet or film in a forming station where a large pressure will form the blister cavity into a negative mold and when the mold is cooled the plastic becomes rigid and maintains its shape. In contrast, Rüdiger teaches a dome 20, which is a concave shape whose distinguishing characteristic is that the concavity faces downward. This disclosure is far too broad to teach or suggest the claimed “*blister bubbles*” feature.

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<sup>8</sup> See Anhäuser, col. 1, lines 6-24.

**C. Dependent Claim 3:**

Dependent claim 3 recites that the cover layer “*consists of a plastic layer laminate*.” The term “*consists of*” limits the cover layer to a plastic layer laminate; *i.e.*, it necessarily excludes cover layers fabricated from non-plastic elements. At least this feature (as recited in claim 3) is not taught or suggested by the prior art relied upon by the Examiner.

In rejecting claim 3, the Examiner relies upon a combination of Anhäuser, Liedtke and Rüdiger. The alleged combination involves (among other things) dispensing with Anhäuser’s protective layer 16 in favor of Rüdiger’s top foil 11 (with domes 20) and bottom foil 13.<sup>9</sup> As pointed out by the Examiner, Rüdiger’s foils 11 & 13 may be lined with a film of inert plastic. But the foils 11 & 13 themselves are fabricated from *metal sheet material*.<sup>10</sup> Consequently, even if combined in the manner suggested by the Examiner, the resultant device would not be relevant to claim 3, which excludes cover layers fabricated from non-plastic elements.

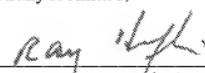
**CONCLUSION**

In view of the above, Applicant earnestly solicits reconsideration and allowance of all of the pending claims.

Pursuant to 37 CFR §§ 1.17 and 1.136(a), Applicant petitions for a one (1) month extension of time for filing a reply to the Office Action and submit the required \$60.00 extension fee herewith.

The Commissioner is authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 50-4446 for any additional fees required under 37 CFR § 1.16 or under 37 CFR § 1.17; particularly, extension of time fees.

Respectfully submitted,

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<sup>9</sup> Office Action, paragraphs 12, 13 and 43.

<sup>10</sup> Rüdiger, col. 3, lines 39-49.